Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 4 Insp GMP 4/15159-0031

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : GLAXO OPERATIONS UK LTD (WARE) T\A GLAXO WELLCOME OPERATIONS

Site address : GLAXO OPERATIONS UK LTD (WARE) T\A GLAXO WELLCOME OPERATIONS, PRIORY STREET, WARE, SG12 0DJ, UNITED KINGDOM

Is an active substance manufacturer that has been inspected in accordance with Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 13/09/2021 , it is considered that it complies with

- The principles of GMP for active substances referred to in Regulation B17 and C17 of the Human Medicines Regulations 2012 (SI 2012/1916)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

- [4000013535] VILANTEROL TRIFENATATE
- [2000008392] SALMETEROL XINAFOATE
- [1000017903] CABOTEGRAVIR
- [2000014516] FLUTICASONE FUROATE
- [4000014056] DOLUTEGRAVIR SODIUM
- [4000014045] UMECLIDINIUM BROMIDE

MHRA-GMDP MHRA

- [2000008220] FLUTICASONE PROPIONATE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

VILANTEROL TRIFENATATE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

SALMETEROL XINAFOATE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

CABOTEGRAVIR

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

FLUTICASONE FUROATE

3.5	General Finishing Steps

MHRA-GMDP MHRA-GMDP MHRA MHRA

	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

DOLUTEGRAVIR SODIUM

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation for GW Manufacturing and Shanghai Desano Chemical
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

UMECLIDINIUM BROMIDE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

FLUTICASONE PROPIONATE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging

MHRA-GMDP

	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

Restrictions or Remarks

Scope of IMP packaging - For product protection purposes only; excludes clinical trial labelling activities

22/02/2022	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

MHRA-GMDP MHRA MHRA-GMDP MHRA